

**REMARKS**

**I. Status of the Application**

Claims 186, 189-194, 197, and 199-203 are pending following amendments to the claims made herein.

**II. Summary of the Telephonic Interview With Examiner Fubara Held 30 May 2008**

Tyler J. Sisk and David A. Casimir, on behalf of Applicants, conducted a telephonic interview with Examiner Fubara on 30 May 2008. Applicants discussed with Examiner Fubara each of the outstanding rejections made in the Office Action mailed 22 January 2008. Applicants pointed out support within the specification for the pending claims, and also provided arguments as to why the cited references failed to render the pending claims obvious.

**III. The Claims Are Supported by the Specification**

The Examiner rejected Claims 186-194, 197, and 199-203 under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. (Office Action at pages 2-3). Applicants respectfully disagree.

Applicants respectfully submit that the Specification provides support for the claims (e.g., for the amount of each components claimed). Specifically, support for 3-15% ethanol can be found on page 21, lines 7-13 and 23; support for 3-15% surfactant can be found on page 21, lines 29-30, and support for 0.5-2% or 1-10% of cetylpyridinium chloride can be found on page 37, lines 26-27; and page 38, lines 24-27, respectively.

Accordingly, no new matter has been added.

Applicants respectfully submit that the Claims are definite and supported by the Specification and request that the Examiner withdraw the rejection under 35 U.S.C. § 112, first paragraph.

**IV. The Claims Are Definite**

The Examiner rejected Claims 186-199 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. (Office Action at page 3). Applicants respectfully disagree.

Nonetheless, without acquiescing to the Examiner's arguments and while reserving the right to prosecute the original or similar claims in the future, Applicants have amended the claims in order to further the prosecution of the application and their business interests.

Specifically, Applicants have amended Claim 186, 200 and 202 to recite "a surface of skin or mucosal cells and tissue of a human." Applicants respectfully submit that the Specification provides ample written description support for these amendments, for example, on page 17, lines 28-29 and page 18, lines 1-2, among other places. Accordingly, no new matter has been added.

Applicants respectfully submit that the amended claims are definite and request that the Examiner withdraw the rejection under 35 U.S.C. § 112, second paragraph.

## **V. The Claims are Not Obvious**

The Examiner rejected Claims 186-194, 197 and 199-203 under 35 U.S.C. §103(a) as allegedly being unpatentable over Libin (U.S. Pat. No. 5,855,872) in view of Stroud et al. (U.S. Pat. No. 6,231,837); and Claims 186-188, 191, 193, 194 and 197-200, 202 and 203 as allegedly being unpatentable over Asculiai et al. (US Pat. No. 4,020,183) in view of Keith et al. (US Pat No. 4,350,707). Applicants respectfully disagree.

In rejecting claims under 35 U.S.C. § 103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness.<sup>1</sup> A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.<sup>2</sup> An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art.<sup>3</sup>

The test for *prima facie* obviousness is consistent with legal principles enunciated in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). The Federal Circuit summarized the Supreme Court's holding in *KSR* that "While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test, the Court acknowledged the importance of identifying 'a **reason** that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination." *Takeda Chem. Indus., Ltd. v. Alphapharma Pty., Ltd.*, 06-1329, slip op. (Fed. Cir. June 28, 2007), at 13-

<sup>1</sup> See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).

<sup>2</sup> *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993).

<sup>3</sup> *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

14 (quoting *KSR*, 127 S. Ct. at 1731) (emphasis added). Although the TSM test should not be applied in a rigid manner, it can provide helpful insight to an obviousness inquiry. *KSR*, 127 S. Ct. at 1731. The *KSR* Court upheld the secondary considerations of non-obviousness, noting that there is “no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis.” *Id.* Additionally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See M.P.E.P. 2143.

Applicants respectfully submit that the cited references, individually or combined, do not teach or suggest each element of the claimed invention. Moreover, Applicants respectfully submit that the limitations of the amended claims exclude the compositions of the cited references.

**A) The Cited References Do Not Teach or Suggest All Limitations of the Claims**

Applicants respectfully submit that the cited references, individually or in combination, do not teach or suggest a method of topically treating a human having a *Herpes simplex I* virus infection, comprising exposing a surface of skin or mucosal cells and tissue of a human to a nanoemulsion composition, or a dilution thereof, the nanoemulsion consisting essentially of 1) a discontinuous oil phase; 2) an aqueous phase; 3) 3-15% by volume ethanol; and 4) 3-15% by volume surfactant; and 5) 0.5-2% or 1-10% by volume halogen-containing compound (e.g., as recited in Claim 186). Similarly, the cited references, individually or in combination, do not teach or suggest a method of topically treating a human having a *Herpes simplex I* virus infection, comprising exposing a surface of skin or mucosal cells and tissue of a human to a nanoemulsion composition, or a dilution thereof, said nanoemulsion composition consisting essentially of: 1) 50-80% by volume oil; 2) distilled water; 3) 3-15% by volume ethanol; 4) 3-15% by volume surfactant; and 5) 0.5-2% or 1-10% by volume cetylpyridinium chloride (e.g., as recited in Claim 200); nor a method of topically treating a human having a *Herpes simplex I* virus infection, comprising exposing a surface of skin or mucosal cells and tissue of a human to a nanoemulsion composition, or a dilution thereof, said nanoemulsion composition consisting of: 1) 3-15% by volume surfactant; 2) 3-15% by volume ethanol; 3) 50-80% by volume oil; 4) cetylpyridinium chloride; 5) distilled water; and 6) ethylenediaminetetraacetic acid (e.g., as recited in Claim 202).

Thus, the cited references, individually or in combination, fail to teach or suggest all the claim limitations.

Applicants further submit that the compositions and methods of using the same disclosed by the cited references are excluded by the limitations of the amended claims.

Thus, Applicants respectfully request that the rejections made under 35 U.S.C. § 103 be reconsidered and withdrawn on the grounds that the references, individually or in combination, do not teach or suggest each and every element of the claimed invention.

### **CONCLUSION**

For the reasons set forth above, it is respectfully submitted that Applicants have addressed all grounds for rejection and Applicants' claims should be passed to allowance. Reconsideration of the application is respectfully requested. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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/Tyler J. Sisk/

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